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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,571	06/26/2003	Richard P. Batycky	2685.2046-003	6287

38421 7590 04/06/2006

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,571	BATYCKY ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *140-144 and 146-173* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *140-144 and 146-173* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 140-144 and 146-173 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 146-150 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, due to the use of the word "substantially," ***is withdrawn***, in view of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 140, 145-147, 149, 151, 156-158, 160, 163-168, 170 and 171 under 35 U.S.C. 102(b) as being anticipated by Radhakrishnan (U.S. patent 5,049, 389) ***is withdrawn***, in light of Applicant's amendments to the claims.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 140-144, 154, and 156-160 are rejected under 35 U.S.C. 102(e) as being anticipated by Tarara et al. (US 2005/0074498).

Tarara discloses engineered particles that may be used for the **delivery of a bioactive agent to the respiratory tract of a patient**. The particles may be used in the form of dry powders or in the form of stabilized dispersions comprising a nonaqueous continuous phase. In particularly preferred embodiments the particles may be used **in conjunction with an inhalation device** such as a dry powder inhaler, metered dose inhaler or a nebulizer (abstract).

Tarara discloses that the disclosed powders may comprise the selected agent or bioactive agent, or agents as the sole structural component of the perforated microstructures. Conversely, the perforated microstructures may comprise **one or more components** (i.e. **structural materials, surfactants, excipients**, etc.) in addition to the incorporated agent [0040].

Tarara discloses that his invented preparations provide highly flowable dry powders that can be efficiently aerosolized, uniformly delivered, and penetrate deeply in the lung or nasal passages [0050]. Any bioactive agents that may be formulated in the perforated microstructures are expressly held to be within the scope of pharmaceutical preparations taught by Tarara, including **bronchodilators and steroids** [0069]. Exemplary medicaments of biologically active agents suitable for used in Tarara's formulations include bronchodilators, such as **adrenaline** [0070]. Adrenaline and epinephrine are synonyms for the same compound.

In preferred embodiments, Tarara's compositions are comprised of microstructures formed by **spray drying** [0075]. The **mean aerodynamic diameter of the perforated microstructures is preferably less than about 5 microns, and in particularly preferred embodiments less than 2 microns**. These particle distributions will facilitate deep lung

deposition of the bioactive agent whether administered using a dry powder inhaler (DPI), metered-dose inhaler (MDI), or nebulizer [0126]. Tarara defines fine particle fraction (FPF) as "the percentage of the total amount of active medicament delivered per actuation from the mouthpiece of a DPI, MDI or nebulizer onto plates 2-7 of an 8 stage Andersen cascade impactor." Tarara's formulations preferably have a **fine particle fraction of approximately 20% or more by weight of the perforated microstructures** (w/w), even more preferably **from about 30 to 70% w/w**. In selected embodiments the present invention will preferably comprise a **fine particle fraction of greater than about 30%, 40%, 50%, 60%, 70% or 80% by weight** [0127].

Tarara states that skilled artisans would appreciate that the perforated microstructures of his invention are useful in DPIs used in inhalation therapies [0131]. Currently, the range of dry powder that can be filled into a unit dose container is from 5 to 15 mg, corresponding to a **drug loading ranging from 25 to 500 micrograms per dose (i.e. actuation)** and bulk reservoir type DPIs can meter between 200 micrograms to 20 mg of powder per actuation [0132].

Tarara discloses that stabilized dispersions of his invented pharmaceutical formulations are particularly suitable for the pulmonary administration of bioactive agents (e.g. adrenaline), which may be used for the **localized or systemic administration of compounds** to any location of the body [0186].

Applicant's attention is drawn to Examples X-XII, wherein Tarara discloses the preparation of various pharmaceutical particles comprising active agents, surfactant, and lactose excipient (Example XI), having a **tap density less than 0.1 g/cm^3**. Surfactants are excipients as well. The Examiner would also like to draw the Applicant's attention to Figure 5 in which

Tarara discloses the distribution of an exemplary particulate composition in an Anderson cascade impactor as delivered by a DPI and a MDI. It is well known in the art that the different stages of the Anderson cascade impactor correlate to the delivery of particles to different regions of the pulmonary system, with stages 6-7 corresponding to delivery of particles to the deep lung (i.e. alveolar region of the pulmonary system). See for example, Radhakrishnan (U.S. Patent No. 5,192,528), where the correlation of the different stages of the Anderson cascade impactor with different regions of the pulmonary system is described.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 140, 145-147, 149, 151, 156-158, 160, 163-168, 170 and 171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radhakrishnan (U.S. patent 5,049, 389) as applied above ***is withdrawn***, due to Applicant's amendments to the claims.

The rejection of claims 140-145, 151, 154-158, 161-168, 170, and 171 under 35 U.S.C. 103(a) as being unpatentable over Maa et al. (U. S. patent 6,284,282) in view of the 56th edition (2002) of the Physicians' Desk Reference (PDR, page 1236) ***is withdrawn***, as a result of Applicant's claim amendments.

The rejection of claims 148 and 149 under 35 U.S.C. 103(a) as being unpatentable over Maa in view of the 56th edition of the Physicians' Desk Reference as applied to claims 140-145,

151, 154-158, 161-168, 170, and 171 above, and further in view of Jakupovic et al. (U.S. patent 6,221,398) **is withdrawn**, in response to Applicant's claim amendments.

The rejection of claims 152, 153, 159, and 169 under 35 U.S.C. 103(a) as being unpatentable over Maa in view of the 56th edition of the Physicians' Desk Reference as applied to claims 140-145, 151, 154-158, 161-168, 170, and 171 above, and further in view of Warren et al. (*Clin. Pharmacol. Ther.*, 1986, *40(6)*, 673-678) **is withdrawn**, due to Applicant's amendments.

The rejection of claims 172 and 173 under 35 U.S.C. 103(a) as being unpatentable over Maa as applied to claims 140-145, 151, 154-158, 161-168, 170, and 171 above, and further in view of Adjei et al. (U.S. patent 6,136,294) and Dobrozsi (U.S. patent application PG-PUB, 2002/0076421) **is withdrawn**, due to Applicant's amendments.

Claims 152-153 and 155 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarara et al. (US 2005/0074498)

Tarara does not anticipate claims 152-153 and 155, because he does not expressly teach the dosage amounts recited in said claims administered in a single inhalation.

It would have been obvious to a person of ordinary skill in the art that Tarara implicitly teaches administration of particles comprising epinephrine administered in a single inhalation, because Tarara teaches that a unit dose container in a DPI may contain from 5 to 15 mg of dry powder, corresponding to a drug loading ranging from 25 to 500 micrograms per dose. It is

obvious that one dose (i.e. actuation) comprises a single inhalation, because the actuation step in the use of a dry powder requires a patient to inhale the medicament composition from the DPI. A skilled artisan would have been aware of the common definition of the terms "inhalation" and "inhaler" as defined in the 2002 *Oxford American Dictionary of Current English* on page 405 as an act of breathing in air; and a portable device used for relieving, especially asthma, by inhaling, respectively.

Claims 161-162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarara et al. (US 2005/0074498) in view of the 56th edition (2002) of the Physicians' Desk Reference (PDR, page 1236) (provided with the previous office action).

The teachings/disclosures of Tarara have been set forth above.

Tarara lacks the teaching of a method of treatment wherein epinephrine is administered to treat anaphylaxis, edema, bronchoconstriction, bronchospasm, and airway constriction.

The 2002 PDR teaches on page 1236 that **epinephrine is essential in the treatment of anaphylaxis** (1st sentence in the section entitled "Precautions"). It also teaches in the "Clinical Pharmacology" section that epinephrine acts to relieve vasodilation and increased vascular permeability. It also **relaxes the bronchial smooth muscles**, which alleviates wheezing and dyspnea. Other conditions alleviated by administration of epinephrine are pruritis, urticaria, and **angioedema** and it may be effective in relieving gastrointestinal and genitourinary symptoms associated with anaphylaxis.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Tarara and the PDR, because Tarara teaches

pharmaceutical preparations wherein the perforated microstructures may comprise adrenaline (i.e. epinephrine) active agent and the PDR describes known treatments which utilize epinephrine to treat anaphylaxis, angioedema, and relax the bronchial smooth muscles. A skilled artisan would have been motivated to combine the prior art references, because the PDR is a well-known medical reference consulted by physicians and other medical professionals to know which medicaments are appropriate to treat which conditions or disorders. A person of ordinary skill in the art would have had a reasonable expectation of success upon combination of the prior art references, because the Tarara teaches pharmaceutical compositions comprising adrenaline and the PDR teaches treatments in which the administration of adrenaline is appropriate.

Claims 140-143, 146-151, 159, 160, and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. (US 2003/0215512) in view of Tarara et al. (US 2005/0074498).

Foster teaches a composition that comprises a mixture of a pharmaceutically acceptable glassy matrix and at least one pharmacologically active material within the glassy matrix. It may be further mixed with a powdered, pharmaceutically acceptable carrier (abstract).

Foster teaches that the powdered composition will be composed of **particles** having a mass median diameter (MMD) of about 1-5 microns and a mass median aerodynamic diameter **(MMAD) of about 1-5 microns** [0051]. The active materials in the composition are active drug substances preferably used for administration via pulmonary inhalation. The unit dosage typically will be between 0.25 mg and 15 mg of total material in the dry powder, wherein the active will comprise **about 0.05% to about 99.0% by weight** of the composition [0054]. In the

dry state the drug or phase containing the active **may be either crystalline or amorphous in form** [0055]. Active small molecules for **systemic and local lung applications** for use in Foster's compositions include steroids and bronchodilators, including **adrenaline** [0056]. Systemic diseases treatable using Foster's compositions are taught in [0060] and pulmonary diseases, which are suitable targets for treatment include, chronic bronchitis, asthma, ARD, COPD, **bronchospasm**, and bronchial asthma [0061]. In addition to the glass former, the composition may contain other additives (i.e. excipients) [0064], including non-polar amino acids (e.g. **leucine**) [0068]. The glass former may be used alone or **in combination with additives, which may be crystalline or amorphous** [0064]. Suitable glass formers include organic carboxylic salts and the most preferable glass formers include **sodium tartrate, lactose, etc.** [0071] to [0072]. In Examples 15-16, Foster teaches exemplary formulations comprising a small molecule active (albuterol). The Tables in [0232] and [0234] obviously disclose a FPF in the column with the heading "% particle mass < 5 microns in size."

Foster lacks the teaching of compositions having a tap density of less than 0.4 g/cm^3.

The teachings of Tarara have been set forth above.

It would have been obvious to a person of ordinary skill in the art at the time of the instant application to combine the teachings of Foster and Tarara, because both inventors teach compositions suitable for inhalation pulmonary administration of active agents, including adrenaline. A skilled artisan would have been motivated to combine the teachings of Foster and Tarara, because Tarara's compositions provide teachings of desirable physical characteristics of aerodynamically light particles especially suitable for inhalation administration. A skilled artisan would have had a reasonable expectation of success upon combination both prior art references

teach adrenaline (i.e. epinephrine) compositions designed for inhalation pulmonary administration.

Claim 171 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tarara et al. (US 2005/0074498) as applied to claims 152-153 and 155 above in view of Radhakrishnan (U.S. patent 5,049,389).

The teachings of Foster and Tarara have been set forth above.

Foster and Tarara lack the express teaching of a composition, which releases the active agent in a sustained manner.

Radhakrishnan teaches a **method for treating a patient in need of epinephrine** by administration of particles comprising a nonphospholipid composition consisting essentially of nonphospholipid components and a drug (adrenaline) aerosolized into aerosol particles having a **mass median aerodynamic diameter smaller than 2.1 μm** and providing a **slow or sustained release of the drug in the lungs** (claims 13 and 15).

Radhakrishnan teaches that the dried particle liposome formulation in the form of dry powder can be prepared either by lyophilization or **spray drying.**

Radhakrishnan teaches that the method of treating a patient is by the **inhalation route of administration** to a person in need of such treatment (claims 13, 18, and 20).

Radhakrishnan discloses that **drug crystallization does not occur outside or inside the liposomes**, nor does sedimentation occur from the suspension (column 13, lines 62-67).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Tarara and Radhakrishnan, because both inventors

teach particulate compositions comprising epinephrine, which is intended for inhalation administration. A skilled artisan would have been motivated to combine the teachings of Tarara and Radhakrishnan to obtain sustained release compositions wherein the active drug and excipients do not crystallize within the liposome and which do not undergo sedimentation when suspended. A person of ordinary skill at the time of the instant invention would have had a reasonable expectation of success upon combination of the prior art references, because both inventors teach particular compositions for inhalation comprising adrenaline.

Claims 163-170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarara et al. (US 2005/0074498) in view of Warren et al. (*Clin. Pharmacol. Ther.*, 1986, *40(6)*, 673-678) (provided with the previous office action).

The teachings of Tarara have been set forth above.

Tarara lacks the express teaching of Cmax and Tmax of different administration routes, specifically inhalation administration vs. non-intravenous injection.

Warren et al. teach that inhalation of 30 puffs of adrenaline (3 mg) from a pressurized aerosol resulted in peak blood plasma levels of adrenaline **(C_{max}) of 4.22 ± 1.93 nM after 1 minute (T_{max}) of administration.** They compared these results to adrenaline administered by a subcutaneous injection, which resulted in peak blood plasma levels of adrenaline **(C_{max}) of 2.43 ± 0.47 nM after 10 minutes (T_{max}) of administration**. The blood plasma levels of adrenaline were used as a measure of the systemic absorption of adrenaline (abstract, Figures 1 and 3 on pages 674 and 675, respectively).

A person of ordinary skill in the art at the time of the instant invention would have been able to obtain information on Warren et al.'s studies showing that the administration of inhaled adrenaline would lead to a shorter time for adrenaline blood plasma levels to reach a maximum concentration as a predictor of what one would expect upon inhalation administration of Tarara's pharmaceutical formulations. A skilled artisan would have known that drug blood plasma levels are a measure of the systemic absorption of a pharmaceutical agent and that said agent would therefore be acting systemically. Based on Warren's data, a person of ordinary skill in the art at the time of the instant invention would have been motivated to administer epinephrine to a patient and would have had a reasonable expectation that said drug administered by inhalation would result in maximal adrenaline blood serum levels in a shorter period of time when compared to non-intravenous injection routes of administration.

Claims 172-173 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. (US 2003/0215512) in view of Tarara et al. (US 2005/0074498) as applied to claims 140-143, 146-151, 159, 160, and 162 above, in further view of the *Drug Information Handbook* (1993) ("DIH").

The teachings of Foster and Tarara have been set forth above.

Foster and Tarara lack the teaching of a composition comprising epinephrine bitartrate.

The use of epinephrine bitartrate would have been readily apparent to a skilled artisan, because it is one of the most common salts of epinephrine employed in pharmaceutical formulations (*Drug Information Handbook*, Lexi-Comp, Inc.: Cleveland, OH, 1993, pp 322-325).

It would have been obvious to a person of ordinary skill in the art to combine the teachings of Tarara and Foster with the DIH, because the DIH is a standard reference used in the pharmaceutical art and the other two prior art references teach pharmaceutical compositions comprising epinephrine. A skilled artisan would have been motivated to combine the teachings of the DIH with those of Tarara and Foster, because epinephrine is a known active agent and epinephrine bitartrate is a common salt of said active used in commercially available pharmaceutical formulations. A person of ordinary skill in the art would have had a reasonable expectation of success upon combination of the prior art references, because all the references teach compositions wherein the active is epinephrine and the bitartrate salt of adrenaline is commonly used in pharmaceutical formulations. Regarding the amount of active agent, Foster teaches an overlapping range for the amount (i.e. about 0.05% to about 99.0% by w/w). In addition, it would have been readily apparent to a skilled artisan per the teachings of Foster that the remainder of the composition would comprise glass-forming excipient (i.e. **sodium tartrate**) and other additives (e.g. **leucine**). The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 140-143, 151, 154, 159, and 160 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 9, 10, 12, 14, 18, 25, and 27 of copending Application No. 10,818,902 in view of Maa et al. (U.S. patent 6,284,282) **is maintained.** The Examiner would like to emphasize that both the instant application and copending '902 have claims drawn to hormone active agents and a tap density less than 0.4 g/cc. Epinephrine (i.e. adrenaline) is a hormone. It is noted that the Applicant cancelled claim 145.

Response to Arguments

Applicant's arguments with respect to claims 140-144 and 146-173 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Claims 140-144 and 146-173 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER